

### **REMARKS**

This responds to the Office Action mailed on March 15, 2004.

Claim 1 is amended and claim 32 is added. As a result, claims 1-3, 14, 15, 19, 28-32 are now pending in this application.

No new matter is added by the amendment of claim 1 or new claim 32. The amendment of claim 1 eliminates text added in the last amendment and clarifies the character of the biologically active mixture. Support will be found in claim 1 as originally filed and in the description of the carrier, pages 7 and 8 of the specification.

The amendment of claim 29 is supported by the specification at page 3, lines 14-17.

New claim 32 is supported by the specification at page 8, lines 24-26.

### **Information Disclosure Statement**

Applicant respectfully requests that a copy of the 1449 Form, listing all references that were submitted with the Information Disclosure Statement filed on August 5, 1998, marked as being considered and initialed by the Examiner, be returned with the next official communication. Applicant has attached a copy of the Information Disclosure Statement as filed on August 5, 1998, along with a copy of the date stamped postcard showing receipt by the U.S. Patent and Trademark Office.

### **§102 Rejection of the Claims**

The Examiner has again rejected claims 1-3, 14, 15, 19, 28-31 under 35 USC § 102(b) as being anticipated by Okada et al (Okada). The Examiner asserts that Okada discloses a water-oil emulsion having a water-soluble drug in the aqueous phase and a polymer in the oil phase. The Examiner points to Example 1 of Okada or the details of this emulsion.

Applicants submit that their claims, as amended, overcome this rejection.

Okada requires that his inner aqueous layer contain the water-soluble drug and “a drug retaining substance therefor”. Okada col. 1, lines 30-32. Okada describes the drug retaining substance as a “substance which is soluble in water and hardly soluble in the organic solvent contained in said oil layer and when dissolved in water assumes a viscous semi-solid consistency

or a substance which gain considerable in viscosity to provide a semi-solid or solid matrix under the influence of an external factor ...”. Okada, col. 4, lines 12-18. Okada provides examples of the drug retaining substance as natural or synthetic mucilages and high molecular weight compounds such as gum acacia, casein, gelatin, collagen, cellulosic polymers and the like. Okada, col. 4, lines 23-38.

Exemplary of this “drug retaining substance” is Okada’s Example 1. This Example discloses that an aqueous gelatin solution is combined with the drug TAP-144. The gelatin is the “drug retaining substance”. The gelatin is the first material to be combined to form Okada’s composition thus showing that it is always present. In fact, gelatin is the “drug retaining substance used in almost all of Okada’s Examples. Other similar “drug retaining substances” are used in the same fashion those Examples not using gelatin.

Applicants’ claims, as amended, exclude such a drug retaining substance from their recited biologically active mixture, which is the aqueous phase of Applicants’ composition. This mixture consists essentially of an aqueous medium and the biologically active agent (drug). The aqueous medium is water or an aqueous solution of water-like consistency. None of such additives for the aqueous medium is capable of acting as a drug retaining substance such that the aqueous medium of Applicants’ composition has or is capable of producing a semi-solid consistency as is required of Okada’s drug retaining substance in his aqueous layer.

For this reason, Applicants submit that their claims, as amended, are not anticipated by Okada.

**CONCLUSION**

Applicants respectfully submit that their claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

RICHARD L. DUNN

By his Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6939

Date

July 2, 2004

By

A. James Nelson

A. James Nelson  
Reg. No. 28,650

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 2nd day of July, 2004.

Name

Dawn M. Poole

Signature

Dawn M. Poole

Receipt is hereby acknowledged for the following in the U.S. Patent and Trademark Office:

In re Application of: DUNN  
For: EMULSIONS FOR IN-SITU DELIVERY SYSTEMS  
Docket No.: 8905.157US01  
Filed: APRIL 14, 1998

Serial No.: 09/060,047  
Due Date: AUGUST 14, 1998 (informal)

- ☒ Date Mailed: August 5, 1998  
☒ Transmittal Sheet in duplicate containing Certificate of Mailing  
☒ Other: Information Disclosure Statement, Form 1449, and copies of cited references  
Return postcard

Patent

AJN:PSTcbb

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Patent

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DUNN  
Examiner: UNKNOWN  
Serial No.: 09/060,047  
Group Art Unit: 1615  
Filed: APRIL 14, 1998  
Docket: 8905.157US01  
Title: EMULSIONS FOR IN-SITU DELIVERY SYSTEMS

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described hereinabove, are being deposited in the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on August 5, 1998.

By:   
Albin J. Nelson

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

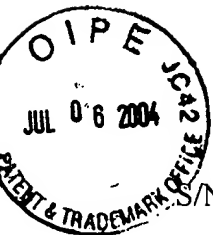
- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Other: Information Disclosure Statement, Form 1449, and copies of cited references
- ☒ Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

MERCHANT, GOULD, SMITH, EDELL,  
WELTER & SCHMIDT  
3100 Norwest Center, Minneapolis, MN 55402  
(612) 332-5300

By: 

Name: Albin J. Nelson  
Reg. No.: 28,650  
AJN:PSTcbb



S/N 09/060,047

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	DUNN	Examiner:	UNKNOWN
Serial No.:	09/060,047	Group Art Unit:	1615
Filed:	APRIL 14, 1998	Docket No.:	8905.157US01
Title:	EMULSIONS FOR IN-SITU DELIVERY SYSTEMS		

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By: 

Albin J. Nelson

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b))

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.


Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialled by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT, GOULD, SMITH, EDELL,  
WELTER & SCHMIDT, P.A.  
3100 Norwest Center  
90 South Seventh Street  
Minneapolis, MN 55402  
612/332-5300

Date: August 5, 1998

  
\_\_\_\_\_  
Albin J. Nelson  
Reg. No. 28,650  
AJN:PSTcbb

FORM 1449\*

## INFORMATION DISCLOSURE STATEMENT

Docket Number:

8905.157US01

Application Number:

09/060,047

## IN AN APPLICATION

(Use several sheets if necessary)

Applicant: DUNN

Filing Date: 04/14/1998

Group Art Unit: 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,759,563	06/02/1998	Yewey et al.			
	5,744,153	04/28/1998	Yewey et al.			
	5,739,176	04/14/1998	Dunn et al.			
	5,733,950	03/31/1998	Dunn et al.			
	5,599,552	02/04/1997	Dunn et al.			
	5,368,859	11/29/1994	Dunn et al.			
	5,368,858	11/29/1994	Hunziker			
	5,340,849	08/23/1994	Dunn et al.			
	5,326,568	07/05/1994	Giampapa			
	5,324,520	06/28/1994	Dunn et al.			
	5,324,519	06/28/1994	Dunn et al.			
	5,286,763	02/15/1994	Gerhart et al.			
	5,278,202	01/11/1994	Dunn et al.			
	5,278,201	01/11/1994	Dunn et al.			
	5,271,961	12/21/1993	Mathiowitz et al.			
	5,250,584	10/05/1993	Ikada et al.			
	5,238,714	08/24/1993	Wallace et al.			
	5,227,157	07/13/1993	McGinity et al.			
	5,192,741	03/09/1993	Orsolini et al.			
	5,188,837	02/23/1993	Domb			
	5,176,907	01/05/1993	Leong			
	5,149,543	09/22/1992	Cohen et al.			
	5,077,049	12/31/1991	Dunn et al.			
	5,049,386	09/17/1991	Eppstein et al.			
	5,019,400	05/28/1991	Gombotz et al.			
	5,013,553	05/07/1991	Southard et al.			
	5,007,940	04/16/1991	Berg			

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.



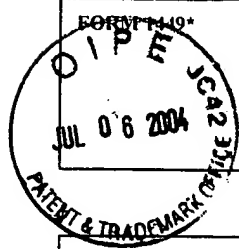
Date Mailed: Aug. 5, 1998

Sheet 2 of 6

<b>FORM 1-1495</b> <b>INFORMATION DISCLOSURE STATEMENT</b> <b>IN AN APPLICATION</b> (Use several sheets if necessary)	Docket Number: 8905.157US01	Application Number: 09/060,047
	Applicant: DUNN	
	Filing Date: 04/14/1998	Group Art Unit: 1615

	4,983,689	01/08/1991	Yu			
	4,981,696	01/01/1991	Loomis et al.			
	4,962,091	10/09/1990	Eppstein et al.			
	4,961,707	10/09/1990	Magnusson et al.			
	4,946,870	08/07/1990	Partain, III. et al.			
	4,942,157	07/17/1990	Gall et al.			
	4,939,131	07/03/1990	Benedict et al.			
	4,938,763	07/03/1990	Dunn et al.			
	B1 4,938,763	07/04/1995	Dunn et al.			
	4,933,182	06/12/1990	Higashi et al.			
	4,932,973	06/12/1990	Gendler			
	4,921,697	05/01/1990	Peterlik et al.			
	4,920,203	04/24/1990	Tang et al.			
	4,919,939	04/24/1990	Baker			
	4,916,241	04/10/1990	Hayward et al.			
	4,912,141	03/27/1990	Kronman			
	4,911,931	03/27/1990	Baylink			
	4,905,680	03/06/1990	Tunc			
	4,904,478	03/27/1990	Walsdorf et al.			
	4,902,296	02/20/1990	Bolander et al.			
	4,897,268	01/30/1990	Tice et al.			
	4,894,373	01/16/1990	Young			
	4,863,472	09/05/1989	Törmälä et al.			
	4,861,627	08/29/1989	Mathiowitz et al.			
	4,857,602	08/15/1989	Casey et al.			
	4,857,456	08/15/1989	Urist			
	4,818,542	04/04/1989	DeLuca et al.			
	4,804,691	02/14/1989	English et al.			
	4,800,219	01/24/1989	Murdoch et al.			
	4,795,804	01/03/1989	Urist			

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Group Art Unit: 1615

	4,793,336	12/27/1988	Wang			
	4,789,732	12/06/1988	Urist			
	4,780,320	10/25/1988	Baker			
	4,774,228	09/27/1988	Seyedin et al.			
	4,774,227	09/27/1988	Piez et al.			
	4,772,470	09/20/1988	Inoue et al.			
	4,767,861	08/30/1988	Boulware			
	4,767,627	08/30/1988	Caldwell et al.			
	4,761,471	08/02/1988	Urist			
	4,745,160	05/17/1988	Churchill et al.			
	4,721,613	01/26/1988	Urquhart et al.			
	4,715,369	12/29/1987	Suzuki et al.			
	4,702,917	10/27/1987	Schindler			
	4,685,883	08/11/1987	Jernberg			
	4,677,139	06/30/1987	Feinmann et al.			
	4,663,077	05/05/1987	Rei et al.			
	4,650,665	03/17/1987	Kronenthal et al.			
	4,631,188	12/23/1986	Stoy et al.			
	4,622,219	11/11/1986	Haynes			
	4,619,989	10/28/1986	Urist			
	4,596,574	06/24/1986	Urist			
	4,595,713	06/17/1986	St. John			
	4,582,640	04/15/1986	Smestad et al.			
	4,570,629	02/18/1986	Widra			
	4,568,536	02/04/1986	Kronenthal et al.			
	4,563,489	01/07/1986	Urist			
	4,526,938	07/02/1985	Churchill et al.			
	4,526,909	07/02/1985	Urist			
	4,491,479	01/01/1985	Lauchenaue			
	4,455,256	06/19/1984	Urist			

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FORM 1449\*

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	4,451,452	05/29/1984	Deibig et al.			
	4,450,150	05/22/1984	Sidman			
	4,447,562	05/08/1984	Ivani			
	4,443,430	04/17/1984	Mattei et al.			
	4,439,420	03/27/1984	Mattei et al.			
	4,408,023	10/04/1983	Gould et al.			
	4,294,753	10/13/1981	Urist			
	4,265,247	05/05/1981	Lenz et al.			
	4,161,948	07/24/1979	Bichon			
	4,148,871	04/10/1979	Pitt et al.			
	3,975,350	08/17/1976	Hudgin et al.			
	3,949,073	04/06/1976	Daniels et al.			
	3,939,111	02/17/1976	Schollenberger et al.			
	3,935,308	01/27/1976	Wise et al.			
	3,931,678	01/13/1976	O'Sullivan et al.			
	3,919,773	11/18/1975	Freeman			
	3,887,699	06/03/1975	Yolles			
	3,767,784	10/23/1973	Gluck			
	3,760,034	09/18/1973	Critchfield et al.			
	3,755,558	08/28/1973	Schribner			
	3,696,811	10/10/1972	Chen			
	3,520,949	07/21/1970	Shepherd et al.			
	3,463,158	08/26/1969	Schmitt et al.			
	3,328,246	06/27/1967	Gottfried et al.			
	3,219,527	11/23/1965	Gurney			
	3,218,283	11/16/1965	Miller			
	3,068,188	12/11/1962	Beste et al.			
	2,155,658	04/25/1939	Herrmann et al.			

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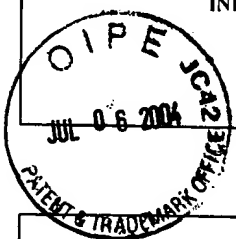
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Applicant: DUNN

Filing Date: 04/14/1998

Group Art Unit: 1615



## FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	1 261 549	09/26/1989	CA				
	0 140 766	05/08/1985	EP				
	0 159 293	10/23/1985	EP			Abstract	
	0 169 016	01/22/1986	EP				
	0 171 173	02/12/1986	EP				
	0 241 178	10/14/1987	EP				
	0 244 118	11/04/1987	EP				
	0 271 831	06/22/1988	EP				
	0 297 535	01/04/1989	EP				
	0 430 474	06/05/1991	EP				
	0 537 559	04/21/1993	EP				
	0 539 751	05/05/1993	EP				
	0 560 014	09/15/1993	EP				
	0 586 838	03/16/1994	EP				
	0 649 662	04/26/1995	EP				
	2 126 270	10/06/1972	FR			Abstract	
	2 635 685	03/02/1990	FR			Abstract	
	29 17 037	04/27/1979	DE			Abstract	
	2 017 113	10/3/1979	GB				
	2 223 027	03/28/1990	GB				
	63-137907	06/09/1988	JP			Abstract	
	WO 85/00969	03/14/1985	PCT				
	WO 85/02092	05/23/1985	PCT				
	WO 89/01006	02/09/1989	PCT				

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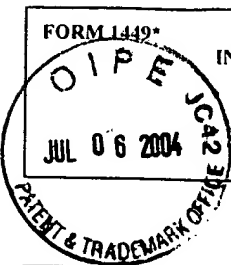
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Applicant: DUNN

Filing Date: 04/14/1998

Group Art Unit: 1615



## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	Gref, R. et al., "Biodegradable long-circulating polymeric nanospheres", <i>Science</i> , 263:1600-1602 (March 18, 1994).
2	Holland, S. et al., "Polymers for biodegradable medical devices. 1. The potential of polyesters as controlled macromolecular release systems", <i>Journal of Controlled Release</i> , 4:155-180 (1986).
3	Juni, K. et al., "Control of release rate of bleomycin from polylactic acid microspheres by additives", <i>Chem. Pharm. Bull.</i> , 33(4):1609-1614 (1985).
4	Ouchi, T. et al., "Synthesis and antitumor activity of conjugates of poly( $\alpha$ -malic acid) and 5-fluorouracils bound via ester, amide or carbamoyl bonds", <i>Journal of Controlled Release</i> , 12:143-153 (1990).
5	Wakiyama, N., et al., "Preparation and evaluation <i>in vitro</i> of polylactic acid microspheres containing local anesthetics", <i>Chem. Pharm. Bull.</i> , 29(11):3363-3368 (1981).
6	Zilch, H., et al., "The sustained release of cefotaxim from a fibrin-cefotaxim compound in treatment of osteitis", <i>Arch. Orthop. Trauma Surg.</i> 106:36-41 (1986).
7	<i>Encyclopedia of Polymer Science and Engineering</i> , John Wiley & Sons Inc., 2:236-237 (1985).
8	Billmeyer, F., <i>Textbook of Polymer Science</i> , 3rd Ed., John Wiley & Sons, pp. 390-391 (1984).
9	<i>Biocompatibility of Clinical Implant Materials</i> (Ch. 9: "Biodegradable Polymers", by D. K. Gilding), pp. 209-232 (date unknown).
10	<i>Hawley's Condensed Chemical Dictionary</i> , 11th Ed. (1987), Van Nostrand Reinhold Company, New York; pp. 145-146, 932-933, 944-945.

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